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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,456	08/24/2000	C. Alan Fu	A-68344-3/RMS/DHR	4376

7590 03/22/2002

FLEHR HOHBACH TEST ALBRITTON & HERBERT LLP
Suite 3400
Four Embarcadero Center
San Francisco, CA 94111-4187

EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/645,456	FU, C. ALAN
	Examiner Robert Landsman	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 January 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 19-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 19-23 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 24 August 2000 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.10.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 1/23/02, has been entered into the record.
- B. The Information Disclosure Statement, filed 5/18/01, has been entered into the record.
- C. Claims 19-23 are pending in the application.

2. Figures

- A. Figure 12 is objected to since it has an extraneous letter "B" typed in the Figure.
- B. Figures 14, 16, 17 and 20 are objected to since they have extraneous letters "B" and "D" typed in the Figure.
- C. The Brief Description of Drawings for Figure 17 recites "Figures A-F." However, Figure 17 is not labeled as parts "A-F."
- D. The Brief Description of Drawings for Figure 19 recites that there are 2 panels. However, Figure 19 only has 1 panel.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 19-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for measuring the interaction of Tnik with NCK and the activation of the JNK pathway, does not reasonably provide enablement for a method for screening for bioactive agents capable of binding, or modulating the activity of, *any and all* cell cycle proteins, or for interfering with the binding of any and all cell cycle proteins with Traf2 or Nck. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive. Applicants have only demonstrated that Tnik can interact, or affect the pathway of Traf2, NCK and JNK and that Tnik did not activate ERK and p38. The only guidance and working examples provided in the specification are drawn toward Tnik. Applicants provide no guidance or working examples of assays using any other cell cycle proteins besides Tnik, nor do they provide guidance or working examples of other cell cycle proteins which can interact with Traf2 or Nck. Furthermore, it is not predictable to one of ordinary skill in the art what other cell cycle proteins would interact with Traf2 or Nck besides those disclosed in the specification and prior art.

Therefore, in summary, due to the excessive breadth of the claims regarding claiming methods of screening bioactive agents capable of binding to all cell cycle proteins, or for screening agents which interfere with the binding of all cell cycle proteins with Traf2 or Nck, along with the lack of guidance and working examples of these methods other than those using Tnik as well as the lack of predictability as to what other cell cycle proteins, other than Tnik, would interact with Traf2 or Nck, leads the Examiner to hold that undue experimentation would be necessary to practice the claimed invention.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 19-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The claims recite only methods of using “cell cycle proteins.” Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Structural features that could distinguish the proteins in the genus of “cell cycle” from others in other protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the

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common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "cell cycle proteins" alone is insufficient to describe the genus.

The specification provides a written description of only a small number of these cell cycle proteins. No other species are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art cannot reasonably visualize or predict the group of proteins which would structurally characterize the genus of cell cycle proteins to be used in the claimed methods, because it is unknown and not described what structurally constitutes the proteins in this genus, including those from any different species, which are further not described; thereby not meeting the written description requirement under 35 USC 112, first paragraph. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 19-23 recite "bioactive agent." However, the metes and bounds of this term are not known. Agents can have numerous bioactivities.

B. Claim 23 is confusing since it is not clear if the "plurality of cells" represents, for example, one petry dish containing many (i.e. a plurality) of cells, or if this phrase means that numerous agents are tested using separate, for example, flasks of cells.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 19 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Suzuki et al. (reference C6 on the IDS filed 1/23/02). The claims recite a method for screening for a bioactive agent capable of binding to, or modulating the activity of a cell cycle protein. Suzuki et al. teach that Tax affects regulatory processes of cells through modulation of cell cycle regulators and that Tax was used in a screening process to determine its effects on various members of the INK4 family (Abstract). Furthermore, Suzuki et al. teach the binding of Tax protein to members of the INK4 family of proteins (first paragraph of "Results" and Figure 1, page 385) and the interaction of Tax on p15ink4b, and its effect of CDK4 activity.

B. Claims 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitamura et al. (reference C2 on the IDS filed 1/23/02). The claims recite a method for screening for a bioactive agent capable of binding to, or modulating the activity of a cell cycle protein. Kitamura et al. teach a screening assay to identify binding proteins which bind to the SH3 domain of the cell cycle protein, Nck, and that various proteins, including p125Nap1 (Abstract) dynamin, and a 140-kDa (first paragraph of "Results and Discussion;" Figures 1 and 3) associated with Nck, or its SH3 domain.

C. Claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Rothe et al. (reference C4 on the IDS filed 1/23/01). The claims recite a method for screening for a bioactive agent capable of binding to, or modulating the activity of a cell cycle protein and a method of screening for a bioactive agent capable of interfering with the binding of a cell cycle protein and Traf2 or Nck. Rothe et al. teach that I-TRAF and c-IAP bind TRAF2 (first full paragraph of page 8244). Since all of these proteins are involved in the cell cycle, the method taught by Rothe et al. meets the limitation of the claims. In addition, Rothe et al. teach that I-TRAF expression in yeast cells inhibits the association of TRAF2 with TNF-R2 and that both I-TRAF and TNF-R2 bind TRAF2 (page 8244, left column second full paragraph). Rothe et al. also teach that I-TRAF could not be coimmunoprecipitated with TNF-R2-TRAF1/2 complex and that TRAF2 cannot bind TNF-R2 and I-TRAF simultaneously. Therefore, since I-TRAF did not bind to the cell cycle protein (TNF-R2) and Traf2 in the method of Rothe et al., the screening method of Rothe et al. meets the limitation of claim 21 since TNF-R2 and Traf2 must have been combined first. The method of Rothe et al. also meets the limitation of claims 19 and 22 since they demonstrate that TRAF2 binds TNF-R2.

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D. Claims 19, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Draetta (WO 95/33819 – reference B1 on the IDS filed 1/23/01). The claims recite a method for screening for a bioactive agent capable of binding to, or modulating the activity of a cell cycle protein as well as a method of screening a library of candidate bioactive agents with a plurality of cells comprising recombinant nucleic acids encoding a cell cycle protein.

Draetta et al. teach a method of screening a library of candidate bioactive agents with a plurality of cells comprising recombinant nucleic acids encoding a cell cycle protein (page 34, lines 18 – page 35, line 3). Draetta et al. have also teach novel proteins which associate with human cyclin dependent kinase 4 (CDK4; page 1, lines 32-33; Figure 2).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
March 18, 2002

Gary L. Kunz
GARY L. KUNZ
SUPPLYORY PATENT EXAMINER
TECHMOL CTR 1600